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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/028,514	02/23/1998	STEPHEN F. GORFIEN	0942.4110002	4800

26111 7590 07/30/2002

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[REDACTED] EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
1651	28

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/028,514	Applicant(s) Gorfien et al.
	Examiner Deborah Ware	Art Unit 1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on May 20, 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3, 6-17, 20-24, 27-37, 73-77, 79-82, 106-109, 112, 140, and 1 is/are pending in the application.
- 4a) Of the above, claim(s) 79-82, 106-109, 112, 143-153, 155, and 156 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3, 6-17, 20-24, 27-37, 73-77, 140, 154, and 157-174 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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1. Applicant's election with traverse of Group I (Claims 1-3, 6-17, 20-24, 27-37, 73-77, 140, 154 and 157-174) in Paper No. 27 is acknowledged. The traversal is on the ground(s) that the search of Group II does not necessarily require a search for recombinant subject matter since Applicants allege that there is no limitation to recombinant subject matter, thus, no serious burden is presented by examination of both groups. This is not found persuasive because the claims of Group II do have a limitation to recombinant subject matter of which art is located in a different class and subclass than art for nonrecombinant subject matter. Therefore, a serious burden has been presented by the subject matter as claimed. However, it is possible that if allowable subject matter has been determined the claims can be rejoined if they are so close in subject matter that the allowance of one group may constitute the allowance of the other based upon the search for Group I. However, at this time the groups are deemed to be different and distinct in that they are searchable in two different areas of classification. The requirement is still deemed proper and is therefore maintained.

2. Claims 79-82, 106-109, 112, 143-153, 155-156 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 27.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e)

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has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1, 2002, has been entered. In addition, the extension of time (3 months) and amendment filed February 1, 2002, have been processed and entered of record in the case. The change of address filed May 10, 2002, is also acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 9-14, 27-29, 31, 33-34, 76, 157, 159-160, 168-174 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims 9-14, 27-29, 31 and 168-174 are rendered vague and indefinite in that the claims fail to set forth proper Markush type language wherein such language should make use of closed terms in the format of --selected from the group consisting of-- and then the ingredients are clearly listed as components of the Markush group and the last component have an "and" preceding it. Also the use of components in parentheses is confusing because it is uncertain whether it is intended to be a part of the listed ingredients or merely an example? More traditional Markush type language is suggested for purposes of clarity.

Claims 33-34 are rendered vague and indefinite for the recitation of "293 embryonic kidney cell" wherein it is unclear whether this is a cell type of what? What does the number "293" refer to? This is especially true since claim 161 refers to "293 cells" as if the number

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represents how many cells are present. Also the phrase "or a derivative thereof" is uncertain and is suggested to be deleted.

Claim 157 and 159-160 are rendered vague and indefinite for the recitation of "a method for replacing protein" since the recited "insulin" and "transferrin" are more clearly defined as growth hormones.

4. Claims 1-3, 6-17, 20-24, 27-37, 73-77, 140, 154 and 157-174 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chessebeuf et al. (A) in view of Shuler et al. (B) and Parenteau et al. (C).

Claims are drawn to methods of culturing mammal cells in a defined medium containing polyanionic or polycationic compounds, and the methods of cultivating are in suspension in vitro. The basic steps are obtaining a mammalian cell and contacting the cell with a serum free, chemically defined culture medium comprising the compounds. The claims are also drawn to method of cultivating cells which do not have to be mammalian cells.

Chessebeuf et al. teach serum free mammalian cell culture medium and methods for culturing cells in a defined medium see col. 6, lines 5-25. See entire document.

Shuler et al. teach suspension culture methods and media therefore. See the abstract. Also note that the reference discloses use of sulfated polyanions for insect cell culture and discloses that dextran sulfate can produce problems for suspension culture of animal cells or mammal cells, note col. 12, lines 1-15. Also note col. 5, line 14, and col. 6, lines 55-67.

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Parenteau et al. teach chemically define cell culture media and methods for culturing mammal cells and the media contains ethanoline, and all of the ingredients of amino acids, salts, vitamins, hormones, etc., Note col. 9-20, all lines.

The claims differ from Chessebeuf et al. in that the compounds are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to replace the dextran as disclosed by Chessebeuf with heparin or some other related and like compound to culture mammal cells as disclosed by Shuler et al. Further, to employ a chemically define culture medium is clearly within the skill of the art as the same is disclosed by Parenteau et al. One of skill would have expected successful results for culturing all of the ingredients disclosed by the secondary reference in a culture medium similar to Chessebeuf et al. since Shuler clearly teaches that there can be problems with dextran sulfate when culturing animal/mammalian cells. The specific ingredients, cell numbers, culture medium, etc. of the specific methods and compositions therefore, are clearly taught, or at least, suggested by the cited combination of prior art. One of skill would have been motivated to exclude dextran sulfate as well. Shuler clearly provides the motivation for one skill to exclude dextran sulfate. Therefore, the claims are *prima facie* obvious over the newly applied art.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

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The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Deborah K. Ware
DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware

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July 27, 2002